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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,840	01/05/2006	Yoshinobu Morimoto	Q88695	2260
65565	7590	05/11/2007		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/540,840	Applicant(s) MORIMOTO ET AL.	
	Examiner Melissa S. Mercier	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-12, 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of Applicant Remarks and Amended Claims filed on March 5, 2007 is acknowledged. Applicant has cancelled claims 13 and 15. Claims 1-12 and 14 are pending in this application.

Applicants' arguments, filed March 5, 2007, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5, 7, 9-10, 12, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Bissett (US PGPub 2001/0012853).

Bissett discloses, "a composition for topical application and for regulating skin condition, including regulating non-melanin discoloration of skin" (paragraph 0031).

According to Bissett, the composition can comprise "N-acetyl-L-Cysteine and derivatives thereof, L-ascorbic acid and derivatives, and tranexamic acid" (paragraphs 0018-0049).

Regarding claims 9-10, the recitation of "a composition for" is interpreted as intended use and therefore not given patentable weight to the claims.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues Bissett does not disclose an actual embodiment or working example specifically containing the combination of (i) tranexamic acid or a salt thereof and (ii) L-Cysteine or a salt thereof. It is the examiners position that the presence or absence of working examples does not render the claims not anticipated by the reference. Bissett discloses the same composition as the instant claims.

Claims 1, 3, 5, 7, 9-10, 12, and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Ancira et al. (US PGPub 2004/0137077).

Ancira discloses, a composition for the treatment of seborrheic keratosis comprising at least one melanin inhibitor. Examples of such melanin inhibitors include gamma-L-Cysteine and tranexamic acid" (paragraph 0034).

With regard to Claims 5 and 7 Ancira teaches, "to aid in moisturizing or conditioning the skin, as will be known to those of skill in the art in view of the instant

disclosure. For example, other ingredients may be added to improve the skin condition or the effectiveness of the compositions. Vitamins may added to the compositions to aid in improving the skin condition thereby inhibiting the production of subsequent cutaneous anomalies after treatment of the original condition" (Ancira, paragraph 0063). Ancira further discloses the vitamin may be L-ascorbic acid (0032).

With regard to claims 12 and 14, Ancira discloses methods of seborrheic keratosis removal, the compositions are also effective in removing other skin conditions such as hyper pigmentation" (paragraph 0062). It is the examiners position that the removal of hyper pigmentation is the same as whitening the skin and treating pigmentations .

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues Ancira does not disclose an actual embodiment or working example specifically containing the combination of (i) tranexamic acid or a salt thereof and (ii) L-Cysteine or a salt thereof. It is the examiners position that the presence or absence of working examples does not render the claims not anticipated by the reference. Ancira discloses the same composition as the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

Art Unit: 1615

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-4, 6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bissett (US PGPub 2001/0012853).

Bissett discloses a L-Cysteine derivative, however, it would be obvious to a person of ordinary skill in the art at the time the invention was made to have used L Cysteine, which would possess the same properties as a derivative.

According to MPEP 2144.05 II A Optimization within Prior Art Conditions or Through Routine Experimentation, differences in concentration will not support the

Art Unit: 1615

patentability of subject matter encompasses by the prior art unless there is evidence indicating such concentrations are critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. "The normal desire of scientist or artisans to improve upon what is already generally known provides the motivation to determine where the disclosed set of percentage ranges is the optimum combination of percentages." (Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382)

Claims 2, 4, 6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ancira et al. (US PGPub 2004/0137077).

With regard to Claims 2, 4, 6, and 8, according to MPEP 2144.05 II A Optimization within Prior Art Conditions or Through Routine Experimentation, differences in concentration will not support the patentability of subject matter encompasses by the prior art unless there is evidence indicating such concentrations are critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. "The normal desire of scientist or artisans to improve upon what is already generally known provides the motivation to determine where the disclosed set of percentage ranges is the optimum combination of percentages." (Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382).

Claims 1-4 and 11 rejected under 35 U.S.C. 103(a) as being unpatentable over Rath (US Patent 6,974,833).

Rath discloses, "compositions and methods for the treatment of diseases or pathological states related to the degradation of the extra cellular matrix" (abstract).

Rath's Table 1 discloses dosages of Components in the Compositions for Oral Administration. The components comprise: tranexamic acid (1-1500 mg/kg BW/d) and Cysteine (0.1-5,000 mg/kg BW/d) (column 6, lines 40-50).

It is generally considered to be prime facie obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose in order to form a composition that is to be used for an identical purpose. The motivation for combining them flows from their having been used individually in the prior art, and from them being recognized in the prior art as useful for the same purpose. As shown by the recited teachings, instant claims are no more than the combination of conventional components of L-Cysteine or its derivatives thereof, all of which are known in the art to be used for the same purpose. It therefore follows that the instant claims define prime facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Conclusion

No claims are allowable. Due to the new grounds of rejection, this action is made Non-Final. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa S. Mercier whose telephone number is

Art Unit: 1615

(571) 272-9039. The examiner can normally be reached on 7:30am-4pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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